DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

M2313N

VIA FEDERAL EXPRESS

Our Reference: 29-54155

January 12, 1999

John D. Mello.
J.D. Mello Dairy
15609 Grangeville Boulevard
Hanford, California 93230

WARNING LETTER

Dear Mr. Mello:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 15, 1998, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On November 2, 1998, you consigned a dairy cow (identified by USDA laboratory report number 208950) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed tetracycline in the kidney at 26.00 parts per million (ppm) and in the liver at 6.10 ppm. The tolerance level for tetracycline for the edible tissues of cattle is 12.00 ppm in the kidneys and 5.00 ppm in the liver.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated

animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their species or class.

4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug RXV brand of Tetracycline Powder 324 within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Labeling for Tetracycline 324 powder does not specify it is approved for use to medicate lactating dairy cattle. Your practice of filling a number 7 size gelatin capsule with tetracycline and inserting it into the uterus of lactating cows for treatment of retained placenta is an unapproved use for which safety and efficacy have not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval. Treating dairy cows with tetracycline powder is likely the cause of the presence of violative levels of tetracycline in the tissues of the animal you sold for food use.

You are using the drug Status SQ brand of oxytetracycline hydrochloride in a manner not in conformance with approved labeling. Labeling of oxytetracycline hydrochloride excludes its use in lactating dairy cows. Your practice of administering 30 mls intravenously in lactating dairy cows for the treatment of coliform mastitis is not in conformance with label directions.

You are using the drug Bimeda brand of penicillin G procaine in a manner not in conformance with approved labeling. Labeling for penicillin G procaine prescribes a dosage of 1 milliliter(ml) per 100 pounds of body weight and warns against using more than 10 mls per injection site. Your practice of administering 25 mls per day in a split dose at multiple sites in a cow results in a dosage in excess of that allowed by the labeling.

Failure to adhere to labeling directions on the drugs you use to treat your dairy cows presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Robert J. Anderson, Investigator, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]